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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,455	12/14/2005	Silvia Gluck	13111-00027-US	3072

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,455	GLUCK ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8-21 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/06;12/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election with traverse of Group I, claim 1-7 and 18-22 on 4/24/08 is acknowledged. The traversal is on the ground(s) that because the same standard of unity of invention was not applied as in the International Preliminary Examination authority and there would be no undue burden on the Examiner, the restriction is improper.

The claims as written are drawn to several inventions which are not linked by a special technical feature to form a single general inventive concept as is required for unity of invention. That no objection to unity of invention was raised in the searching process in the PCT prosecution is not binding in the present case.

In addition, the question of burden of search is not an issue in restrictions in cases filed under 35 U.S.C § 371.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite, confusing in denoting certain parenthetical DSM numbers. These numbers are not found in the DSMZ Catalogue on line.

Claim 1 is vague, indefinite and confusing in the recitation of "an expanded substrate spectrum", since it is unclear what the base line substrate spectrum is intended to be. Moreover, it is unclear how the "substrate spectrum" is expanded in this context. If a particular enzyme is

intended, the claims should be amended accordingly. In addition, the intended meaning of "which isomerizes at least one further alpha-hydroxy carboxylic acid of the formula (I)" is uncertain in this context, since the material isomerized is not identified with any particularity.

Claim 1 is confusing in the recitation of " if appropriate, isolating the resultant isomer mixture or a resultant second stereoisomer or removing the resultant second stereoisomer from the reaction equilibrium". The "isomer mixture", "a resultant second stereoisomer" and "the reaction equilibrium" intended are not clearly defined in this context. Furthermore, it is unclear under which circumstances the alternatives of the process are to be "appropriate".

Claims 2, 4-6 lack antecedent basis in claim 1 for "cell extract" or "intact cells". It is noted that "cell extract" and "intact cells" are a source of enzyme but not an enzyme *per se*.

Claim 18 is vague and indefinite in that the meaning of "essentially removed" is uncertain in this context". Moreover, claim 18 lacks clear antecedent basis in claim 1 for this limitation.

Claim 19 is confusing in lacking antecedent basis for "reaction mixture obtained". In addition, the "subsequent reaction" recited is not defined.

Claim 20 lacks clear antecedent basis for "the resultant stereoisomer of the alpha-hydroxy carboxylic acid".

Claims 2, 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that "cell extract" and "intact cells" are a source of enzyme but not an enzyme *per se*.

Claims 1-7 and 18-22 are incomplete in the absence of a clear recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *L. paracasei, L. delbrueckii, L. sakei* and *L. oris.* It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 8 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Felfer *et al. (*Journal of Molecular Catalysis B: Enzymatic 15 (2001) 213–222).

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase.

Felfer *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase. See, e.g., Scheme 2 and Results and discussion.

Claims 1-2 and 7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Gluck *et al.*

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase.

Gluck *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase. See, e.g., Abstract.

Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schnell *et al.*

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase.

Schnell *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase. See, e.g., Figure 1.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dennis *et al.* , (Annals of the New York Academy of Sciences, July 1965, Vol. 119, No. 3 : Pages 868-876) .

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase.

Dennis *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase. See, e.g., page 873.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hiyama *et al.* (*J Biochem.* 1968; 64: 99-107).

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase, optionally using *Lactobacillus.*.

Hiyama *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase from *Lactobacillus sake (sakei)*. See, e.g., page 106.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stetter *et al.*, (Arch Mikrobiol. 1973 Dec 31;94(3):221-47.) in light of DSMZ Catalogue.

The claims are directed to the microbiological isomerization of α-hydroxy carboxylic acids using a racemase, optionally using *Lactobacillus.*.

Stetter *et al.* teach the microbiological isomerization of α-hydroxy carboxylic acids using a racemase from various *Lactobacillus* strains. See, e.g., Table 3, page 227 and Figure, page 237. That these strain is DSM 20017 is shown by DSMZ Catalogue.

Claims 1-7 and 18-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Felfer *et al.* taken with Hiyama *et al.,* Stetter *et al.,* DSMZ Catalogue, Mori *et al.* and Seufer-Wasserthal *et al.(*U.S. Patent No. 5,534,436).

The claims are directed to a process of treating an α-hydroxycarboxylic acid with a racemase and optionally isolating the mixture obtained and chemical or enzymatically treating it further.

Each of Felfer *et al.,* Hiyama *et al.,* Stetter *et al.* and Mori *et al.* disclose a process of treating an α-hydroxycarboxylic acid with a racemase. In addition, Hiyama *et al.* and Stetter *et al.* teach the use of *Lactobacillus* strains DSM 20207 and DSM 20017 in the process, such as *L. paracasei* subsp. *paracasei* and *L. sakei,* as adequately demonstrated by DSMZ Catalogue, see, e.g., item 906, which is the Stetter *et al.* reference.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success of isomerizing various alpha-hydroxycarboxylic acids using microbial racemases, including the racemases obtained from the specific strains recited, including *L. paracasei* subsp. *paracasei* DSM 20207 and *L. sakei* 20017 known to possess suitable racemase activity.

The references differ from the invention as claimed in that further enzymatic or chemical modifications are not recited. However, Mori *et al.* adequately show that it was well known in the art at the time the claimed invention was made to modify compounds obtained in isomerization reaction or resolution reactions by converting a racemic compound into an optically active isomer. See, e.g., Examples. In addition, Seufer-Wasserthal *et al.* disclose the chemical or enzymatic enantionselective subsequent reaction that comprises esterification. See, e.g., col. 2, bridging paragraph between col. 2 and 3.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Felfer *et al.,* Hiyama *et al.,* Stetter *et al.* and Mori *et al.* by using a variety of substrates and/or racemases and submitting the resultant product to further reactions such as esterification as suggested by the teachings of Mori *et al.* and Seufer-Wasserthal *et al.* for the expected benefit of obtaining pharmaceutically valuable optically active compounds that are important *per se* or which are useful intermediates to produce further optically active pharmaceuticals.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651